

SENATE BILL 786

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CF HB 714

By: Senators Montgomery and Forehand, Forehand, Astle, Garagiola, Glassman, Kelley, Kittleman, Klausmeier, Mathias, Middleton, Muse, and Pugh

Introduced and read first time: February 4, 2011
Assigned to: Finance

Committee Report: Favorable with amendments
Senate action: Adopted
Read second time: March 25, 2011

CHAPTER _____

1 AN ACT concerning

2 **Health – Newborn Screening Program – Critical Congenital Heart Disease**

3 FOR the purpose of requiring ~~that the Department of Health and Mental Hygiene's~~
4 ~~Newborn Screening Program include screening for critical congenital heart~~
5 ~~disease~~ the Department of Health and Mental Hygiene to adopt certain federal
6 recommendations on critical congenital heart disease screening in newborns
7 under certain circumstances; requiring the State Advisory Council on
8 Hereditary and Congenital Disorders to develop certain recommendations for
9 critical congenital heart disease screening of newborns in the State; requiring
10 the Advisory Council to convene certain experts to provide certain information;
11 requiring the Advisory Council to examine the impact of implementing
12 mandatory critical congenital heart disease screening; requiring the Advisory
13 Council to review certain studies and literature; requiring the Advisory Council
14 to submit a certain report to certain committees of the General Assembly on or
15 before a certain date; and generally relating to the State Advisory Council on
16 Hereditary and Congenital Disorders and newborn screening for critical
17 congenital heart disease.

18 BY repealing and reenacting, with amendments,
19 Article – Health – General
20 Section 13–111
21 Annotated Code of Maryland
22 (2009 Replacement Volume and 2010 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 Preamble

2 WHEREAS, Congenital heart disease is the most common birth defect and
3 affects approximately eight out of every 1,000 infants each year; and

4 WHEREAS, More than 36,000 infants are born with congenital heart disease
5 each year in the United States; and

6 WHEREAS, Congenital heart disease is the leading cause of death for infants
7 born with a birth defect despite survival rates now approaching 96% for all affected
8 children; and

9 WHEREAS, A major cause of infant mortality as a result of congenital heart
10 disease is that a significant number of children affected are not detected as having
11 heart disease in the newborn nursery; and

12 WHEREAS, An effective newborn screening mechanism for congenital heart
13 disease before newborns leave the nursery can reduce infant mortality; and

14 WHEREAS, Pulse oximetry has been shown to be an effective screening test to
15 detect congenital heart disease before infants leave the newborn nursery; and

16 WHEREAS, Children's National Medical Center has worked with Holy Cross
17 Hospital to become leaders in the implementation of pulse oximetry screening in
18 community nurseries; and

19 WHEREAS, The Secretary of Health and Human Services' Advisory Committee
20 for Heritable Disorders in Newborns and Children recommended the addition of
21 screening for critical cyanotic congenital heart disease to the core panel for universal
22 screening of all newborns in the United States; now, therefore,

23 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
24 MARYLAND, That the Laws of Maryland read as follows:

25 **Article – Health – General**

26 13–111.

27 (a) The Department shall establish a coordinated statewide system for
28 screening all newborn infants in the State for certain hereditary and congenital
29 disorders associated with severe problems of health or development, except when the
30 parent or guardian of the newborn infant objects.

31 (b) Except as provided in § 13–112 of this subtitle, the Department's public
32 health laboratory is the sole laboratory authorized to perform tests on specimens from

1 newborn infants collected to screen for hereditary and congenital disorders as
2 determined under subsection (d)(2) of this section.

3 (c) The system for newborn screening shall include:

4 (1) Laboratory testing and the reporting of test results; ~~and~~

5 (2) Follow-up activities to facilitate the rapid identification and
6 treatment of an affected child; ~~AND~~

7 ~~(3) SCREENING FOR CRITICAL CONGENITAL HEART DISEASE.~~

8 (d) In consultation with the State Advisory Council on Hereditary and
9 Congenital Disorders, the Department shall:

10 (1) Establish protocols for a health care provider to obtain and deliver
11 test specimens to the Department's public health laboratory;

12 (2) Determine the screening tests that the Department's public health
13 laboratory is required to perform;

14 (3) Maintain a coordinated statewide system for newborn screening
15 that carries out the purpose described in subsection (c) of this section that includes:

16 (i) Communicating the results of screening tests to the health
17 care provider of the newborn infant;

18 (ii) Locating newborn infants with abnormal test results;

19 (iii) Sharing newborn screening information between hospitals,
20 health care providers, treatment centers, and laboratory personnel; and

21 (iv) Delivering needed clinical, diagnostic, and treatment
22 information to health care providers, parents, and caregivers; and

23 (4) Adopt regulations that set forth the standards and requirements
24 for newborn screening for hereditary and congenital disorders that are required under
25 this subtitle, including:

26 (i) Performing newborn screening tests;

27 (ii) Coordinating the reporting, follow-up, and treatment
28 activities with parents, caregivers, and health care providers; and

29 (iii) Establishing fees for newborn screening that do not exceed
30 an amount sufficient to cover the administrative, laboratory, and follow-up costs
31 associated with the performance of screening tests under this subtitle.

1 (E) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, IF THE
2 SECRETARY OF HEALTH AND HUMAN SERVICES ISSUES FEDERAL
3 RECOMMENDATIONS ON CRITICAL CONGENITAL HEART DISEASE SCREENING OF
4 NEWBORNS, THE DEPARTMENT SHALL ADOPT THE FEDERAL SCREENING
5 RECOMMENDATIONS.

6 SECTION 2. AND BE IT FURTHER ENACTED, That:

7 (a) The State Advisory Council on Hereditary and Congenital Disorders shall
8 develop recommendations on the implementation of critical congenital heart disease
9 screening of newborns in the State in accordance with this section.

10 (b) The Advisory Council shall:

11 (1) convene experts from the State's academic medical centers and any
12 other hospital that the Advisory Council considers appropriate, as well as other State
13 organizations and professional groups, to provide information for the development of
14 recommendations for critical congenital heart disease screening of newborns in the
15 State;

16 (2) examine the impact of implementing mandatory critical congenital
17 heart disease screening, including an examination of costs, insurance reimbursement,
18 necessary medical equipment and staff training, screening protocols and quality
19 oversight, and risk of harm; and

20 (3) review medical and public health studies and literature across a
21 broad range of newborn delivery systems with respect to critical congenital heart
22 disease screening of newborns.

23 (c) On or before December 31, 2011, the Advisory Council shall submit its
24 findings and recommendations on the implementation of critical congenital heart
25 disease screening of newborns in a report to the Senate Finance Committee and the
26 House Health and Government Operations Committee, in accordance with § 2-1246 of
27 the State Government Article.

28 (d) Notwithstanding any recommendation developed by the Advisory Council
29 under this section, if the Secretary of Health and Human Services issues federal
30 recommendations on critical congenital heart disease screening of newborns, the
31 Department shall adopt the federal screening recommendations in accordance with §
32 13-111(e) of the Health – General Article as enacted by this Act.

33 SECTION ~~2~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take
34 effect July 1, 2011.